

## Exhibit 3



*Questions and Answers  
for Transplant Candidates about*

# Lung Allocation

## **Who are UNOS and the OPTN?**

United Network for Organ Sharing (UNOS) is a non-profit charitable organization that manages the nation's transplant system — known as the Organ Procurement and Transplantation Network (OPTN)— under contract with the federal government. As the OPTN, UNOS helps create and define organ sharing policies that make the best use of donated organs. This process involves continuously evaluating new advances and discoveries so policies can be adapted to best serve patients waiting for transplants.

All transplant programs and organ procurement organizations throughout the country are OPTN/UNOS members and are obligated to follow the policies the OPTN creates for allocating organs.

## **What is the lung allocation system?**

Every lung transplant candidate age 12 and older receives an individualized lung allocation score (for specifics on pediatric lung allocations, see p. 3). The lung allocation score is an important factor in determining priority for receiving a lung transplant when a donor lung becomes available. The lung allocation system determines the order of everyone awaiting a lung transplant by their lung allocation score, blood type, and the distance between the candidates and the hospital where the lung donor is located. Age also plays a role because lungs from pediatric (ages 0-11) and adolescent (ages 12-17) donors are offered first to pediatric and adolescent transplant candidates before they are offered to adults.

The lung allocation system uses medical information about each lung transplant candidate. This information includes lab values, test results, and disease diagnosis. This medical information is used to calculate a lung allocation score from 0 to 100 for each transplant candidate. The lung allocation score estimates the severity of each candidates' illness and his or her chance of success following a lung transplant. All candidates are placed in order for compatible lung offers according to their score: a candidate with a higher lung allocation score will receive higher priority for a lung offer when a compatible lung becomes available in the same geographic zone.

## Transplant candidates' lung allocation scores are calculated from the following medical information:

- **Forced vital capacity** – A lung function test that measures the maximum amount of air you can breathe in as deeply as possible. This amount may be lower in patients with lung disease.
- **Pulmonary artery pressure** – The pressure the heart generates to pump blood through the lungs. This pressure may be high in some people with serious lung disease.
- **Oxygen at rest** – The amount of oxygen needed at rest to maintain adequate oxygen levels in the blood. People with severe lung disease may need additional oxygen.
- **Age** – Age at the time lungs are offered.
- **Body mass index** – A measure of body fat based on height and weight that, when combined with other medical test results, helps assess health status.
- **Diabetes** – High blood sugar over a long period of time may be a predictor of health status in some people with lung disease.
- **Functional status** – A way to measure the effects that lung disease has on performing routine daily tasks.
- **6-minute walk distance** – How far you can walk in 6 minutes is a measure of functional status.
- **Assisted ventilation** – The use of a ventilator to assist breathing is a measure of disease severity.
- **Pulmonary capillary wedge pressure** – The pressure that blood returning to the heart from the lungs must overcome. This pressure can become increased when the heart is not pumping effectively.
- **Serum creatinine and change in serum creatinine** – A measure of kidney function. High creatinine levels reflect impaired kidney function, sometimes associated with severe lung disease.
- **Diagnosis** – Research has shown that urgency among people needing a lung transplant and success following a lung transplant vary among people with different lung diseases. Therefore, diagnosis factors into the calculation of the lung allocation score.
- **PCO<sub>2</sub> and change in PCO<sub>2</sub>** – The amount of carbon dioxide in the blood. When the lung's ability to exchange oxygen and carbon dioxide becomes impaired, the PCO<sub>2</sub> level may increase.
- **Total bilirubin and change in bilirubin** – A substance made by the liver when it breaks down old red blood cells. High bilirubin is a marker for right heart failure.
- **Cardiac index** – Indicates how well the heart is pumping blood. Low cardiac index indicates failure of the heart to maintain adequate blood circulation.
- **Central venous pressure** – The blood pressure in the veins in the right upper chamber of the heart. High CVP may indicate failure of the heart to maintain adequate blood circulation.

The supply of donor lungs is limited. This allocation system effectively uses the limited number of donor lungs and has reduced the number of deaths of people waiting for a transplant. The OPTN designed the lung allocation score system by studying scientific data on lung transplantation and by drawing on experience with many types of lung diseases.

### **Do pediatric candidates receive a lung allocation score?**

Lung candidates under the age of 12 are not prioritized by lung allocation scores. Instead pediatric lung candidates are classified as Priority 1 or Priority 2, based on their medical condition. Those that meet criteria reflecting a more urgent status are listed a Priority 1. All other lung candidates in this age range are Priority 2. A candidate's pediatric priority is used along with blood type and distance from the donor hospital to determine the order for making offers to lung candidates.

### **What does the lung allocation system mean for me?**

The lung allocation system is responsive to your individual medical needs. It helps determine when you will receive an offer for donor lungs based on your particular medical information. Your lung allocation score or pediatric priority status is based on your own medical information. It reflects the seriousness of your medical status before transplant and your likelihood of a successful transplant.

### **How is waiting time used in the lung allocation system?**

Waiting time plays a very limited role when allocating lungs to transplant candidates 12 years and older. Candidates receive lung offers based mainly on the lung allocation scores or pediatric priority status for those candidates younger than 12 years old. Waiting time is used to break ties when two or more lung candidates have the same lung allocation score or pediatric priority status, and these candidates are in the same geographic zone.

## **How do I register as a lung transplant candidate under the lung allocation system?**

Your transplant team will decide when to register you for a lung transplant. When that time comes, you will need a complete transplant work-up. During the transplant work-up, you will undergo a series of medical tests that your transplant center needs to register you as a candidate for lung transplantation. This same information is used to calculate your lung allocation score.

## **How often should my medical information be updated?**

Your transplant team must update most of your medical information every six months. If your lung allocation score is 50 or higher, your transplant center will also update your assisted ventilation, supplemental oxygen and current PCO<sub>2</sub> information every 14 days. Since the lung allocation system uses your medical information to compute your lung allocation score, it is important that your transplant center has your most current information and test results. Your transplant center may also update your information in the system any time your physician thinks it is necessary to reflect a change in your condition.

*Updating Pediatric Priority 1 Data:* Transplant centers must update the medical information for pediatric Priority 1 candidates at least once every six months. Every six months the system will check to see if a Priority 1 candidate's medical information has been updated. If a center has not updated a candidate's information within that six-month window, the candidate will revert to Priority 2 until their information is updated.

**Important:** If your medical information is not kept up-to-date, it will negatively affect your lung allocation score. It is important for you to work with your transplant team to set up a schedule for visits that will allow the team to keep your information up-to-date.

### **What is the Lung Review Board?**

*The Lung Review Board is a national group of transplant physicians and surgeons who review requests from transplant centers to grant priority in exceptional cases when the transplant team believes that the assigned lung allocation score or pediatric priority status does not represent the severity of the case. The Lung Review Board looks at the details of each case with the name of the patient and transplant center omitted and decides whether to approve or deny the request.*

### **What if I cannot perform a required test?**

Much of the medical information that is needed to calculate your lung allocation score comes from diagnostic tests or medical procedures. If your transplant team decides that you should not undergo these tests or procedures because of the severity of your condition, your physician may supply an estimate of your medical information to be entered in the system to the Lung Review Board. The Lung Review Board will evaluate your doctor's request and determine if it is appropriate to use estimated information in the system instead. Otherwise, the system will substitute default values.

### **What if my doctors do not agree with my lung allocation score or pediatric priority?**

If your transplant physician or surgeon believes that your lung allocation score does not adequately reflect your needs, then your transplant center may ask the Lung Review Board to review your situation. Similarly, if a transplant physician or surgeon feels that a lung candidate younger than 12 has a medical condition comparable to Priority 1, but does not meet one of the criteria listed in policy, they may ask the Lung Review Board to review the pediatric candidate's situation. The Lung Review Board will consider your special circumstances and decide whether to approve or deny the request.

### **Will the lung allocation system change in the future?**

This system was designed to be flexible and allow for improvements. In organ transplantation, as in all scientific fields, new studies are taking place all the time to learn how to save more lives and how to help people live longer and fuller lives. The lung allocation system is reviewed regularly. Adjustments are made to the way lung allocation scores are calculated to better meet the needs of transplant candidates. Your transplant team will keep you informed of changes to the system and what you may need to do.

### **What if I have more questions?**

If you have any further questions or concerns, you should contact your transplant team. You may also contact UNOS Patient Services at 1-888-894-6361. Details about allocation policy and patient information resources are available on the following websites:

[www.optn.transplant.hrsa.gov](http://www.optn.transplant.hrsa.gov)

[www.unos.org](http://www.unos.org)

[www.transplantliving.org](http://www.transplantliving.org)



*Our mission is to advance organ availability and transplantation  
by uniting and supporting its communities for the benefit of patients  
through education, technology and policy development.*



[www.unos.org/social](http://www.unos.org/social)

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